Proposed Rule Making

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 981]

ALMONDS GROWN IN CALIFORNIA

Salable, Reserve, and Export Percentages for 1972–73 Crop Year

Notice is hereby given of a proposal to establish, for the 1972–73 crop year, which began July 1, 1972, salable, reserve, and export percentages of 55, 45, and 100 percent, respectively, applicable to California almonds. The proposed percentages would be established in accordance with the provisions of the marketing agreement, as amended, and Order No. 981, as amended (7 CFR Part 981; 37 F.R. 3983), regulating the handling of almonds grown in California, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The proposal was unanimously recommended by the Almond Control Board.

All persons who desire to file written data, views, or arguments in connection with the aforesaid proposal should file the same, in quadruplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, to be received not later than August 28, 1972. All written submissions made pursuant to this notice will be made available for public inspection at the office of the hearing clerk during official hours of business (7 CFR 1.27(b)).

The proposed percentages are based upon the following estimates (kernel weight basis) for the crop year beginning July 1, 1972:

(1) Production of 180 million pounds;

(2) Trade demand for domestic almonds of 85 million pounds (which is based on a total demand of 85.2 million pounds less 200,000 pounds of imports for consumption);

(3) Handler carryover of 18.7 million pounds on July 1, 1972;

(4) Desirable handler carryover of 32.7 million pounds on June 30, 1973;

(5) Trade demand and desirable handler carryover requirements for 1972 crop almonds of 99.0 million pounds (items 2 plus 4 minus 3);

(6) 81.0 million pounds of reserve almonds (item 1 minus item 5);

(7) Export requirements of 75.0 million pounds of reserve almonds;

(8) Reserve carryover of 6.0 million pounds on June 30, 1973, needed for export during the period July 1, 1973, through August 31, 1973 (which is based on a total reserve carryover of 6.1 million pounds minus 100,000 pounds of reserve carry-in on June 30, 1972); and

(9) Total export requirements of 81.0 million pounds from 1972 crop (item 7 plus item 8).

On the basis of the foregoing estimates, salable, reserve, and export percentages of 55, 45, and 100 percent, respectively appear to be appropriate for the 1972–73 season.

The proposal is as follows:

§ 981.222 Salable, reserve, and export percentages for almonds during the crop year beginning July 1, 1972.

The salable, reserve, and export percentages during the crop year beginning July 1, 1972, shall be 55, 45, and 100 percent, respectively.

Dated: August 14, 1972.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.72-13989 Filed 8-17-72;8:46 am]

[7 CFR Part 991]

HOPS OF DOMESTIC PRODUCTION

Proposed Expenses and Rate of Assessment for 1972–73 Marketing Year

Notice is hereby given of a proposal regarding expenses of the Hop Administrative Committee for the 1972–73 marketing year and rate of assessment for that marketing year, pursuant to §§ 991.55 and 991.56 of Order No. 991, as amended (7 CFR Part 991). The amended marketing order regulates the handling of hops of domestic production, and is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674).

The Hop Administrative Committee has recommended for the 1972–73 marketing year beginning August 1, 1972, a budget of expenses in the total amount of $166,300 and a rate of assessment of 0.3 cent per pound of salable hops. Expenses in that amount and the rate of assessment are specified in the proposal hereinafter set forth.

All persons who desire to submit written data, views, or arguments in connection with the aforesaid proposal should file the same, in quadruplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, to be received not later than August 29, 1972. All written submissions made pursuant to this notice will be made available for public inspection at the Office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The proposal is as follows:

§ 991.307 Expenses of the Hop Administrative Committee and rate of assessment for the 1972–73 marketing year.

(a) *Expenses.* Expenses in the amount of $166,300 are reasonable and likely to be incurred by the Hop Administrative Committee during the marketing year beginning August 1, 1972, for its maintenance and functioning and for such purposes as the Secretary may, pursuant to the provisions of this part, determine to be appropriate.

(b) *Rate of assessment.* The rate of assessment for said marketing year, payable by each handler in accordance with § 991.56, is fixed at 0.3 cent per pound of salable hops.

Dated: August 15, 1972.

CHARLES R. BRADER,
Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.72-14032 Filed 8-17-72;8:49 am]

DEPARTMENT OF COMMERCE

Maritime Administration

[46 CFR Part 381]

CARGO PREFERENCE

Uniform Chartering Procedure

In F.R. Doc. 72-11703, appearing in the FEDERAL REGISTER issue of July 29, 1972 (37 F.R. 15318) giving notice that the Assistant Secretary of Commerce is considering the promulgation of certain regulations under the Cargo Preference Act of 1954, section 901(b) of the Merchant Marine Act, 1936, as amended (46 U.S.C. 1241(b)), the return date for submission of views and comments by interested persons was stated as "on or before August 21, 1972."

Said notice is hereby amended by deleting the date of "August 21, 1972" and substituting therefor the date of "September 15, 1972."

By order of the Assistant Secretary of Commerce for Maritime Affairs.

Dated: August 16, 1972.

JAMES S. DAWSON, Jr.,
Secretary, Maritime Administration.

[FR Doc.72-14122 Filed 8-17-72;8:51 am]

National Oceanic and Atmospheric Administration

[50 CFR Part 260]

QUALITY CONTROL SYSTEMS

Statement of Policy and Intent

AUGUST 14, 1972.

On pages 9328 through 9331 of the FEDERAL REGISTER of May 9, 1972, there was published a statement of policy and intent which encouraged official establishments to develop and implement complete or partial programs for quality control. Appendices to the statement contained, (1) proposed Guidelines for Development of Quality Control Systems—Official Establishments and, (2) proposed Guidelines for Assessment and Approval of Quality Control Systems—Official Establishments.

Interested persons were given 60 days in which to submit comments regarding the proposed guidelines. Few comments of a substantive technical nature were received. All indicated agreement in principle with the basic objectives and intent of the quality control program. However, one comment stated that the guidelines implied too rigid a concept of quality control, and suggested that instead of requiring strict adherence to the proposed guidelines, each system be evaluated on its own merits. Another comment suggested a modification of the plan with provision made for an agreed period of time for companies to attain compliance. One comment requested clarification of pertinent reports and quality control records that would be made available to the National Marine Fisheries Service (NMFS).

In response to the foregoing comments, the following clarifications are made: (1) Quality control plans should be developed in a simple, disciplined manner, and should not be unnecessarily rigid. Quality control systems will be assessed on their individual merits and demonstrated effectiveness, with the expectation that the plan has been developed using standard quality control principles and terms. During the onsite assessment of a quality control system, the official establishment quality control official will be invited to accompany the NMFS survey team. (2) Official establishment reports pertinent to use by NMFS are those recorded findings resulting from the performance of examinations and tests designated in the quality control plan. Such information and results provide part of the basis for product certification.

NMFS plans to use the guidelines as presently issued, until such time as changes are indicated. As experience in the use of the guidelines develops, further review and modification may be necessary, and subsequently will be undertaken with due notice to NMFS inspection service users with a corresponding opportunity for comment. It should be noted that NMFS policy provides for partial as well as complete quality control systems; and since implementation of a quality control program is voluntary at official establishments, processors may proceed with developing and implementing a quality control program as their resources permit.

JOSEPH W. SLAVIN,
Acting Director,
National Marine Fisheries Service.

[FR Doc.72-14002 Filed 8-17-72;8:47 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 273]

BIOLOGICAL PRODUCTS

Procedures for Review of Safety, Effectiveness, and Labeling

The importance to the American public of safe and effective vaccines, serums, blood, and other analogous biological products cannot be understated. As early as 1902, Congress enacted biologics control provisions in the Public Health Service Act. These provisions were revised and codified in section 351 of the Public Health Service Act of 1944. A regulatory program has been developed under this congressional mandate, whereby manufacturers of biological products are licensed to distribute these products with adequate showing that they are pure, potent, and safe for their intended uses.

Section 351 of the Public Health Service Act does not explicitly confer the authority to deny or revoke a license on the ground that the product is ineffective or misbranded. Because all biological products are drugs, and because the Federal Food, Drug, and Cosmetic Act does contain explicit authority to control the effectiveness and misbranding of all drugs, applicable provisions of the Federal Food, Drug, and Cosmetic Act were redelegated, as published in the FEDERAL REGISTER on February 25, 1972 (37 F.R. 4004), for use to control these aspects of biological products. Shortly thereafter a review of the effectiveness of all licensed biologics was announced, with the first category to consist of certain bacterial vaccines and bacterial antigens, as published in the FEDERAL REGISTER of March 15, 1972 (37 F.R. 5404). On July 1, 1972, the Division of Biologics Standards, National Institutes of Health, which has been charged with administering and enforcing section 351 of the Public Health Service Act, was transferred to the Food and Drug Administration, where it is now the Bureau of Biologics (37 F.R. 12865). As part of this transfer, the February 25, 1972, redelegation has been rescinded.

The Commissioner of Food and Drugs, in accepting the transfer of responsibilities for the regulation of biological products, concluded that a systematic review of present procedures should be undertaken.

This proposal will establish a procedure under which the safety, effectiveness, and labeling of all biological products presently licensed under section 351 of the Public Health Service Act will be reviewed. Advisory review panels comprised of independent experts will provide their conclusions and recommendations to the Commissioner of Food and Drugs, who then will review and implement them. Although these products have been reviewed for safety in the past, it is concluded that the safety of these products should be reviewed again at this time, not only because a review of effectiveness requires a consideration of safety factors, but also because new safety criteria have been developed relating to the necessity for long term scientific evaluation, in that long periods of time may pass before latent adverse effects become manifest. The use of independent advisory panels to participate in this review will insure objective review of these past decisions, and thus will assure public confidence in the use of these products.

The review procedure proposed in this notice relies for legal authority on both the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. To the extent that licensed biological products are presently not required to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, these regulations supersede any such exemptions. As the provisions of the Federal Food, Drug, and Cosmetic Act are gradually applied to licensed biological products and new biological products such existing exemptions will be modified or revoked for a biological product or category of products, on a transitional basis.

The Commissioner of Food and Drugs is aware of the unique problems involved in applying the requirement of "substantial evidence of effectiveness" to biological products, under the Federal Food, Drug, and Cosmetic Act. Where adequate and well-controlled studies are not feasible, and acceptable alternative scientific methods of demonstrating effectiveness are available, the latter will be sufficient. The advisory review panels convened under the procedure proposed in this notice will initially develop the standard and methodology for effectiveness for a particular class of biological products, taking into account all of the circumstances involved, subject to review by the Commissioner of Food and Drugs.

The review procedure proposed in this notice represents the first amalgamation of the licensing procedure established under section 351 of the Public Health Service Act and the new drug and misbranding provisions established under the Federal Food, Drug, and Cosmetic Act. Each review panel will determine those biological products that are and are not safe, effective, and not misbranded, as well as those for which further study is required. The applicable product licenses will then be confirmed, revoked, or permitted to remain in effect on an interim basis pending further study.

The review procedure proposed in this notice encompasses the overall safety and effectiveness of the biological product. The purity and potency of individual lots of a safe and effective biological product will continue to be handled on a lot-by-lot basis pursuant to the requirements already established in 21 CFR Part 273.

All biological products must be licensed prior to marketing, and there are no exemptions or grandfather clauses. It is possible that some biological products are excluded from the definition of a "new drug" under the 1938 or 1962 grandfather clauses, but no biological product is exempt from the misbranding or adulteration provisions of the Federal Food, Drug, and Cosmetic Act. Accordingly, product licenses for products that are determined by the Commissioner of Food and Drugs, on the basis of the recommendations of the applicable advisory review panel, to be either not safe and effective or misbranded, will be revoked.

This notice constitutes only the first step in bringing together the provisions of section 351 of the Public Health Service Act and the requirements of the Federal Food, Drug, and Cosmetic Act. New procedural and substantive regulations governing the licensing of biological products, which will incorporate all applicable provisions of the Federal Food, Drug, and Cosmetic Act, are in preparation and will be proposed for comment when they are available.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042, as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371), the Public Health Service Act (sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262), and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243, as amended; 5 U.S.C. 553, 702, 703, 704), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that 21 CFR Part 273, formerly 42 CFR Part 73, be amended by adding a new section, as follows:

§ 273.245 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

For purposes of reviewing biological products that have been licensed prior to July 1, 1972, to determine that they are safe and effective and not misbranded, the following regulations shall apply, and and prior administrative action exempting biological products from the provisions of the Federal Food, Drug, and Cosmetic Act is superseded to the extent that these regulations result in imposing requirements pursuant to provisions therein for a designated biological product or category of products.

(a) *Advisory review panels.* The Commissioner of Food and Drugs shall appoint advisory review panels (1) to evaluate the safety and effectiveness of biological products for which a license has been issued pursuant to section 351 of the Public Health Service Act, (2) to review the labeling of such biological products, and (3) to advise him on which of the biological products under review are safe, effective, and not misbranded. An advisory review panel shall be established for each designated category of biological product. The members of a panel shall be qualified experts, appointed by the Commissioner, and may include persons from lists submitted by organizations representing professional, consumer, and industry interests. The Commissioner shall designate the chairman of each panel, and summary minutes of all meetings shall be made.

(b) *Request for data and views.* (1) The Commissioner of Food and Drugs will publish a notice in the FEDERAL REGISTER requesting interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products. The license for any biological product falling within the category shall promptly be revoked if no such submission is made. (2) Data and information submitted pursuant to a published notice, and falling within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j), shall be handled by the advisory review panel and the Food and Drug Administration as confidential until publication of a proposed evaluation of the biologics under review and the full report or reports of the panel. Thirty days thereafter such data and information shall be made publicly available and may be viewed at the Office of the Hearing Clerk of the Food and Drug Administration, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of one or more of those statutes. (3) To be considered, eight copies of the data and/or views on any marketed biological product within the class must be submitted, preferably bound, indexed, and on standard sized paper, approximately 8½ x 11 inches. The time allotted for submission will ordinarily be 60 days. When requested, abbreviated submissions should be sent. All submissions shall be in the following format, indicating "none" or "not applicable" where appropriate, unless changed in the FEDERAL REGISTER notice:

BIOLOGICAL PRODUCTS REVIEW INFORMATION

I. Label or labels and all other labeling (preferably mounted. Facsimile labeling is acceptable in lieu of actual container labeling.)

II. Representative advertising used during the past 5 years.

III. The complete quantitative composition of the biological product.

IV. Animal safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

C. Finished biological product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

V. Human safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished biological product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the safety of the finished biological product.

5. Pertinent medical and scientific literature.

VI. Efficacy data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination on the efficacy of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the effectiveness of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished biological product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the effectiveness of the finished biological product.

5. Pertinent medical and scientific literature.

VII. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the biological product and its components and the scientific basis (or lack thereof) for the conclusion that the biological product, including its components, has been proven safe and effective and is properly labeled for the intended use or uses. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary shall be included.

VIII. If the submission is by a licensee, a statement signed by the person responsible for the submission must be included, stating that to the best of his knowledge and belief, it includes all information, favorable and unfavorable, pertinent to an evaluation of the safety, effectiveness, and labeling of

the product, including information derived from investigation, commercial marketing, or published literature. If the submission is by an interested person other than a licensee, a statement signed by the person responsible for such submission must be included, stating that to the best of his knowledge and belief, it fairly reflects a balance of all the information, favorable and unfavorable, available to him pertinent to an evaluation of the safety, effectiveness, and labeling of the product.

(c) *Deliberations of an advisory review panel.* An advisory review panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations to the Commissioner of Food and Drugs with respect to the safety, effectiveness, and labeling of the biological products in the designated category under review.

(1) A panel may also consult any individual or group.

(2) Any interested person may request in writing an opportunity to present oral views to the panel. Such written requests for oral presentations should include a summarization of the data to be presented to the panel. Such request may be granted or denied by the panel.

(3) Any interested person may present written data and views which shall be considered by the panel. This information shall be presented to the panel in the format set forth in paragraph (b) (3) of this section and within the time period established for the biological product category in the notice for review by a panel.

(d) *Standards for safety, effectiveness, and labeling.* The advisory review panel, in reviewing the submitted data and preparing the panel's conclusions and recommendations, and the Commissioner of Food and Drugs, in reviewing and implementing the conclusions and recommendations of the panel, shall apply the following standards to determine that a biological product is safe and effective and not misbranded.

(1) Safety means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipent at the time. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the biological product is safe under the prescribed conditions of use, including results of significant human experience during use.

(2) Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological or other effect of the biological product, when used under adequate directions for use and warnings against unsafe use, will serve a clinically significant function in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 130.12(a) (5) (ii) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the biological product or essential to the validity of the investigation, and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

(3) The benefit-to-risk ratio of a biological product shall be considered in determining safety and effectiveness.

(4) A biological product may combine two or more safe and effective active components: (i) When each active component makes a contribution to the claimed effect or effects; (ii) when combining of the active ingredients does not decrease the purity, potency, safety, and effectiveness of any of the individual active components; and (iii) if the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent preventive therapy or treatment for a significant proportion of the target population.

(5) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall comply with section 351 of the Public Health Service Act and sections 502 and 503 of the Federal Food, Drug, and Cosmetic Act, and in particular with the applicable requirements of §§ 273.600 through 273.605 and 1.106 of this chapter.

(e) *Advisory review panel report to the Commissioner.* An advisory review panel shall submit to the Commissioner of Food and Drugs a report containing the panel's conclusions and recommendations with respect to the biological products falling within the category covered by the panel. Included within this report shall be:

(1) A statement which designates those biological products determined by the panel to be safe and effective and not misbranded. This statement may include any condition relating to active components, labeling, tests required prior to release of lots, product standards, or other conditions necessary or appropriate for their safety and effectiveness.

(2) A statement which designates those biological products determined by the panel to be unsafe or ineffective, or to be misbranded. The statement shall include the panel's reasons for each such determination.

(3) A statement which designates those biological products determined by the panel not to fall within either subparagraph (1) or (2) of this paragraph on the basis of the panel's conclusion that the available data are insufficient to classify such biological products, and for which further testing is therefore required. The report shall recommend with as much specificity as possible the type of further testing required and the time period within which it might reasonably be concluded. The report shall also recommend whether the product license should or should not be revoked, thus permitting or denying continued manufacturing and marketing of the biological product pending completion of the testing. This recommendation will be based on an assessment of the potential benefits and risks likely to result from the continued use of the product for a limited period of time while the questions raised concerning the product are being resolved by further study.

(f) *Proposed order.* After reviewing the conclusions and recommendations of the advisory review panel, the Commissioner of Food and Drugs shall publish in the FEDERAL REGISTER a proposed order containing:

(1) A statement designating the biological products in the category under review that are determined by the Commissioner of Food and Drugs to be safe and effective and not misbranded. This statement may include any condition relating to active components, labeling, tests required prior to release of lots, product standards, or other conditions necessary or appropriate for their safety and effectiveness, and may propose corresponding amendments in other regulations under this Part 273.

(2) A statement designating the biological products in the category under review that are determined by the Commissioner of Food and Drugs to be unsafe or ineffective, or to be misbranded, together with the reasons therefor. All licenses for such products shall be proposed to be revoked.

(3) A statement designating the biological products not included in either of the above two statements on the basis of the Commissioner of Food and Drugs determination that the available data are insufficient to classify such biological products under either subparagraphs (1) or (2) of this paragraph. Licenses for such products may be proposed to be revoked or to remain in effect on an interim basis. Where the Commissioner determines that the potential benefits outweigh the potential risks, the proposed order shall provide that the product license for any biological product falling within this paragraph will not be revoked but will remain in effect on an interim basis while the data necessary to support its continued marketing are being obtained for evaluation by the Food and Drug Administration. The tests necessary to resolve whatever safety or effectiveness questions exist shall be described.

(4) The full report or reports of the panel to the Commissioner of Food and Drugs. The summary minutes of the panel meeting or meetings shall be made available to interested persons upon request. Any interested person may, within 60 days after publication in the FEDERAL REGISTER, file with the Hearing Clerk of the Food and Drug Administration written comments in quintuplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the office

of the Hearing Clerk during regular working hours, Monday through Friday.

(g) *Final order.* After reviewing the comments, the Commissioner of Food and Drugs shall publish in the FEDERAL REGISTER a final order on the matters covered in the proposed order. The final order shall become effective as specified in the order.

(h) *Additional studies.* (1) Within 30 days following publication of the final order, each licensee for a biological product designated as requiring further study to justify continued marketing on an interim basis, pursuant to paragraph (f)(3) of this section, shall satisfy the Commisssioner of Food and Drugs in writing that studies adequate and appropriate to resolve the questions raised about the product have been undertaken, or the Federal Government may undertake the studies. The Commissioner may extend this 30-day period if necessary to review and act on proposed protocols. If no such commitment is made or adequate and appropriate studies are not undertaken, the product license or licenses shall be revoked.

(2) A progress report shall be filed on the studies every January 1 and July 1 until completion. If the progress report is inadequate or if the Commissioner of Food and Drugs concludes that the studies are not being pursued promptly and diligently, or if interim results indicate the potential benefits do not outweigh the potential risks, the product license or licenses shall be revoked.

(3) Promptly upon completion of the studies undertaken on the product, the Commissioner of Food and Drugs will review all available data and will either retain or revoke the product license or licenses involved. In making this review and evaluation the Commissioner may again consult the advisory review panel, which prepared the report on the product, or other advisory committees, professional organizations, or experts. The Commissioner shall take such action by notice published in the FEDERAL REGISTER.

(i) *Court appeal.* The final order published pursuant to paragraph (g) of this section, and any notice published pursuant to paragraph (h) of this section, constitute final agency action from which appeal lies to the courts. The Food and Drug Administration will request consolidation of all appeals in a single court. Upon court appeal, the Commissioner of Food and Drugs may, at his discretion, stay the effective date for part or all of the final order or notice, pending appeal and final court adjudication.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: August 14, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-13998 Filed 8-17-72;8:47 am]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Parts 2, 89, 91, 93]

[Docket No. 18302]

AUTOMOTIVE VEHICLE LOCATOR SYSTEMS IN LAND MOBILE RADIO SERVICES

Further Notice of Inquiry; Extension of Time

In the matter of inquiry as to Automotive Vehicle Locator Systems in the Land Mobile Radio Services involving Parts 2, 89, 91, and 93 of the Commission's rules. Docket No. 18302, RM-1734.

1. The Department of Transportation (DOT) has requested an extension of time of 90 days for the filing of comments and replies in the above-captioned proceeding, published July 12, 1972 (37 F.R. 13640).

2. In support of its request, DOT states that it is now conducting a series of vehicle location tests and evaluations, the results of which will not be available until early September. DOT states that these results are essential for it to be able to provide comprehensive and meaningful comments in reply to the further notice of inquiry.

3. It appears that the public interest would be served by granting the additional 90 days asked to afford the petitioner and other interested parties a full opportunity for the preparation and presentation of their views in this inquiry to aid the Commission in evaluating the issues raised therein.

4. *Accordingly, it is ordered,* Pursuant to § 0.331(b)(4) of the Commission's rules, that the time for filing comments in the above-captioned proceeding is extended from September 14, 1972, to December 14, 1972, and for reply comments from September 28, 1972, to December 28, 1972.

Adopted: August 8, 1972.

Released: August 10, 1972.

[SEAL] JAMES E. BARR,
Chief, Safety and Special Radio Services Bureau.

[FR Doc.72-13080 Filed 8-17-72;8:45 am]